IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-KAJ
	)	(consolidated)
	)	
	)	**REDACTED PUBLIC VERSION**

PLAINTIFFS' REPLY MEMORANDUM SUPPORTING MOTION SEEKING RETURN OR DESTRUCTION OF PRIVILEGED DOCUMENTS

ASHBY & GEDDES
Steven J. Balick (I.D. # 2114)
John G. Day (I.D. # 2403)
Tiffany Geyer Lydon (I.D. #3950)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
Tel: 302-654-1888
Fax: 302-654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Kurt G. Calia
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Dated: November 7, 2006

Plaintiffs, Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Plaintiffs"), submit this Reply supporting Plaintiffs' motion (D.I. 308) asking the Court to compel the return of two documents that contain privileged information, but were inadvertently produced by Plaintiffs in unredacted form: (1) the "Life Cycle Opportunity Plan" (hereinafter, "LCO Plan") (JAN RAZ 0192627-641), and (2) a summary of a draft Janssen license agreement (hereinafter "Licensing Summary") (JAN RAZ 0177809-812). These documents contain clearly privileged information that was provided by or at the direction of Plaintiffs' in-house patent counsel for the purpose of conveying legal advice regarding the intellectual property landscape associated with galantamine and regarding draft provisions of a license agreement. Other redacted portions of the documents contain information that is irrelevant to the present litigation and not part of discovery by agreement of the parties.

Defendants' opposition seeks to circumvent the firmly-established public policy warranting the exclusion from discovery of privileged communications. Defendants' unsupported rhetoric simply cannot justify its refusal to return or destroy the unredacted versions of the LCO Plan and Licensing Summary: Defendants provide no compelling factual or legal support for their positions and mislead the Court by misstating the provisions of the Stipulated Protective Order and overlooking applicable principles of privilege law.[1]

---

[1] Although Defendants take issue with the fact that Plaintiffs filed the present motion rather than contacting Chambers to schedule a telephone conference (*see* Defendants' Response in Opposition to Plaintiffs' Motion Seeking Return or Destruction of Privileged Documents (D.I. 312; hereinafter "Def. Opp.") at 2.), the Stipulated Protective Order expressly requires that upon a receiving party's refusal to return inadvertently produced documents or information, a motion be filed to ask the Court to compel the return of such material. (*See* Stipulated Protective Order, ¶ 29(b).)

The redacted portions of the documents at issue are properly excluded from discovery under the attorney-client privilege and by agreement between the parties. Because the Defendants have no right to Plaintiffs' privileged communications either under applicable law or in light of public policy endorsing a party's right to withhold privileged communications, Plaintiffs' motion should be granted and Defendants ordered to return to Plaintiffs or destroy all copies of the unredacted versions of the LCO Plan and the Licensing Summary.

I. Defendants' Recitation of the Law is Misleadingly Incomplete.

Although Defendants' recitation of case law is marginally correct, it is incomplete in material respects. In particular, Defendants oft-repeated refrain that factual or scientific information cannot be protected by attorney-client privilege is overly-simplistic and thus misleading. In support of this argument, Defendants cite *Upjohn Co.* v. *United States*, 449 U.S. 383 (1981), and focus on the following language: "the protection of the privilege extends only to communications and not to facts." (Def. Opp. at 4, *quoting Upjohn*, 449 U.S. at 395-96.) Defendants neglect to include the very next sentence from *Upjohn*, which clarifies that a "fact is one thing and a communication concerning that fact is an entirely different thing." *Upjohn* at 395-96. Defendants' assertions to the contrary notwithstanding, a document is not necessarily discoverable simply because a document contains some public or non-confidential factual information. *Knogo Corp.* v. *United States*, 213 U.S.P.Q. 936, 941, (1980) ("If an attorney-client communication could be discovered if it contained information known to others, then it would be the rare communication that would be protected and, in turn, it would be the rare client who would freely communicate to an attorney.")

Similarly, Defendants quote *Smithkline Beecham Corp.* v. *Apotex Corp.*, 232 F.R.D. 467 (E.D. Pa. 2005), in support of the axiomatic proposition that the attorney-client privilege applies "where employees secure legal, not business, advice or services." (Def. Opp. at 4, *quoting Smithkline,* 232 F.R.D. at 479.) What Defendants fail to point out is that the *Smithkline* Court also rejected the argument that certain conveyances of scientific or technical information were not privileged, holding instead that "[w]here client and counsel share technical information, that communication is privileged as long as it was made for the purpose of securing legal advice or legal services, or conveying legal advice." *Smithkline* at 480-81. Because the nature and purpose of the communication is relevant to whether privilege applies, Defendants' "facts cannot be privileged" oversimplification should be rejected.

Defendants further obfuscate the relevant issues in this dispute by stating that Plaintiffs have not informed them as to where the documents in question originated, and arguing that "in many European countries, communications with in-house counsel are not privileged." In support, Defendants cite two cases that determined that neither France nor Switzerland recognize an attorney-client privilege for in-house counsel. (Def. Opp. at 4 *citing In re Rivastigmine*, 237 F.R.D 69 (S.D.N.Y 2006) (Switzerland); *Bristol-Myers Squibb Co.* v. *Rhone-Poulenc Rorer*, 188 F.R.D. 189 (S.D.N.Y. 1999) (France).) The only non-US attorney responsible for content in the LCO Plan and Licensing summary is Filip Verhoeven, who is Janssen's in-house counsel from its Leuven, Belgium offices, and is registered with *Institut des Juristes d'enterprise / Instituut voor Bedrijfsjuristen*. (Herridge Aff. at ¶¶ 4, 7, attached hereto as Exhibit A.) To the extent that Belgian law is applicable, it extends confidentiality privilege to communications from registered in-house counsel provided within the framework of their activity as legal counsel. *See* Loi du 1er mars 2000 créant un Institut des Juristes d'entreprise (Moniteur Belge du 4 juillet 2000).

Defendants' enigmatic focus on Swiss and French law, rather than Belgian law, appears to be nothing more than a diversion.

Worse than Defendants' incomplete and extraneous recitation of the law is their misapplication of the law to the relevant facts, which Plaintiffs demonstrate below.

II. Life Cycle Opportunity Plan (JAN RAZ 0192627 - JAN RAZ 0192641)

A. Plaintiffs Have Not Waived Privilege With Respect to the Redacted Portions of the LCO Plan.

Apparently realizing the weakness of their arguments on the merits of Plaintiffs' privilege assertions, Defendants resort to the argument that Plaintiffs' request for the return or destruction of the LCO Plan was untimely.[2] Defendants' waiver argument is equally unavailing.

Defendants mistakenly assert that Plaintiffs do not dispute that the LCO Plan was marked and used during the June 28, 2006 deposition of Christina Kauffman. To the contrary, Plaintiffs do, in fact, dispute that Defendants made use of any privileged information from the document – and indeed Defendants do not (and cannot) disagree. As Plaintiffs explained in their opening Memorandum ("Plaintiffs' Mem."; D.I. 309), defense counsel asked Ms. Kauffman only a handful of questions concerning non-privileged information related to the creation of the LCO Plan and a sales figure on its second page. (Plaintiffs' Mem., Ex. E, Kaufman Dep. at 149-158.) Defense counsel made absolutely no use of the privileged information in the document, and

---

[2] Defendants' timeliness argument smacks of hypocrisy, as Defendants themselves have repeatedly disregarded the timing provisions of the Stipulated Protective Order. Defendants' own Statement of Facts makes clear that despite the fact that Paragraph 29(b) of the Stipulated Protective Order allows them 14 days to respond to a written request for the return or destruction of an inadvertently produced document, they waited until September 22, 2006 to initially assert their purported "good faith basis" for refusing to return the LCO Plan, and waited over a full month to reserve the right to raise issues related to Plaintiffs' underlying privilege assertions.

would have been able to complete the very same questioning with the redacted version that Plaintiffs later supplied them.

Courts have long recognized the importance of protecting privileged communications for the purpose of ensuring full and competent legal representation of parties in our judicial system. The fundamental policy underlying the attorney-client privilege is "to encourage full and frank communication between attorneys and their clients." *United States* v. *Zolin*, 491 U.S. 554, 562, (1989). "The privilege is vain if it does not secure freedom of professional consultation. Unless the confidence is inviolate, there will of necessity be restraints upon communication working grievous injury and injustice." *State* v. *Kociolek*, 129 A.2d 417, 425 (N.J. 1957). For this reason, a finding of waiver is a harsh result that is rarely granted. *Wolhar* v. *General Motors Corp.*, 712 A.2d 457, 463 (Del. Super. Ct. 1997) ("The weight of authority in this and other jurisdictions holds that waiver of privilege should be granted only in cases of the most egregious conduct by the party claiming the privilege."); *see also United States* v. *Ortland*, 109 F.3d 539, 549 (9th Cir. 1997) ("Precisely because the privilege is so critical, it should be deemed waived only in the most express of circumstances.").

Plaintiffs have produced nearly 225,000 pages of documents in this litigation and made hundreds of thousands of additional pages available for inspection. The expedited discovery schedule in effect placed additional pressure upon the process, and thus it should surprise no one that a few privileged documents were inadvertently produced by parties on both sides of the dispute. *See F.S.B.* v. *First Bank System*, 902 F.Supp. 1356, 1363 (D. Kan. 1995), *rev'd on other grounds*, 101 F.3d 645 (10th Cir. 1996) (considering an expedited discovery schedule as a factor in its decision against imposing waiver of attorney-client privilege).

Upon the Defendants initial attempt to question one of Plaintiffs' witnesses regarding the privileged portions of the LCO Plan, Plaintiffs immediately acted to provide a properly redacted replacement and to request the return of the inadvertently produced full version. (Plaintiffs' Mem., Ex. F, Truyen Dep. at 125-133 and 172-179.) Under the circumstances here presented, there is simply no justifiable reason to impose the severe penalty of waiver upon Plaintiffs based on Defendants limited earlier questioning related only to the non-privileged portions of the LCO Plan.

B. The Redacted Portions of the LCO Plan Contain Privileged Content.

Defendants overreach when they argue that factual or scientific information should inexorably be treated as non-privileged. As explained above, this stance is incorrect and contradicted by established law. Defendants' rhetoric aside, the privileged nature of the redacted portions of the LCO Plan is self-evident, as they plainly involve legal strategy and analysis regarding the intellectual property landscape associated with galantamine. Plaintiffs have confirmed that Janssen's in-house U.S. counsel, Mary Appollina, and Janssen's Belgian patent agent (Luc Quaghebeur) acting at the direction of its Belgian in-house counsel (Filip Verhoeven), were responsible for the redacted content, which was provided for the purpose of conveying legal advice. (Herridge Aff. at ¶ 4.) Plaintiffs also confirm that Ms. Appollina had ultimate responsibility for the redacted content. (*Id.*)

Apparently believing that repetition can make a baseless argument convincing, Defendants spend eleven full pages listing excerpts of the LPO Plan and then restating, without further analysis or legal support, their argument that the excerpts contain non-privileged factual or scientific information. Rather than burdening the Court with an unnecessary eleven-page rebuttal, Plaintiffs set forth below a few examples to illustrate the obviously privileged nature of several of the excerpts that defendants selected.

REDACTED

Defendants curiously deem this excerpt as non-privileged in that it contains "general factual information about a patent." (Def. Opp. at 8-9.) To the contrary, this section plainly contains an evaluation by counsel of the scope and duration of patent protection, including a legal opinion related to the likelihood than a patent term extension will be awarded. This is a communication of legal advice of precisely the sort that the attorney-client privilege was intended to protect.

REDACTED

Here again, Defendants make the conclusory statement that "general factual information about various patent applications in this context is not privileged." (Def. Opp. at 9-10.) Aside from the fact that Defendants offer no information about what they mean by the qualifier "in this context," the above-quoted excerpt clearly includes legal analysis and strategy developed by counsel

REDACTED

Moreover, this section included the opinion of counsel regarding the scope of patent coverage, a matter of law and an issue upon which counsel is customarily consulted. *See Markman* v. *Westview Instruments Inc.*, 517 U.S. 370 (1996) (holding that claim construction "is exclusively within the province of the court."). And, as explained in detail below, the last portion of this

communication relates clearly to issues of galantamine synthesis, which by the parties' agreement is not the subject of discovery in this case.

REDACTED

Defendants astoundingly characterize this section as containing "scientific information, not legal information." In addition to the legal opinion regarding the scope of patent coverage, this excerpt contains counsel's patentability analysis, and as such, clearly constitutes a privileged attorney-client communication. *See In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 805 (Fed. Cir. 2000) (ruling that scientific and technical information submitted to in-house counsel for purpose of obtaining patentability determination was privileged communication "made for the purpose of obtaining legal advice").

In each instance set forth above, and indeed in several other excerpts supplied by Defendants, the information that Plaintiffs redacted from the LCO Plan concern counsels' evaluation of patent scope, patentability, prior art, and other aspects of the intellectual property landscape associated with galantamine, provided to scientists and executives at Janssen for the purpose of conveying legal advice and properly excluded from discovery under the attorney-client privilege.

C. The Redacted Portions of the LCO Plan Contain Information Irrelevant to This Litigation, and Excluded From Discovery by Agreement of the Parties.

Defendants make only a few passing references in footnotes to the fact the parties have agreed in this litigation that no discovery will be taken with regard to (1) products other than the subject of Janssen's IND/NDA (relating to Razadyne IR) and Defendants' ANDAs seeking approval for a generic version of Razadyne IR, and (2) information related to galantamine synthesis and product formulation. (*See* Ex. B, Calia Mar. 10, 2006 letter to

Defense Counsel; Ex. C, Apr. 17, 2006 email to Donovan.) Indeed, Mustafa Hersi, counsel for the Barr Defendants, acknowledged during the Rule 30(b)(6) deposition of Janssen (of Dr. Luc Truyen) that information regarding other products or combinations of other products are not discoverable in this case per the parties' agreement. (Plaintiffs' Mem., Ex. F, Truyen Dep. at 132:1-8.) Several of Plaintiffs' redactions from the LCO Plan are based on the parties' agreement, and Defendants are not at liberty to disregard that agreement now that fact discovery is closed.

Set forth below are several excerpts from the LCO Plan that Defendants argue are not privileged. Although Plaintiffs believe that these excerpts do, in fact, contain privileged information, there is certainly no doubt that they concern matters excluded from discovery under the above-described agreement between the parties.

REDACTED

This section clearly refers to a potential product not within the scope of Janssen's IND/NDA for Razadyne IR, and therefore, properly excluded from discovery. Nevertheless, Defendants argue that this information should be discoverable because their expert relied upon it in formulating his expert report. (Def. Opp. at 10.)

This argument is unavailing, as on September 26, 2006, Plaintiffs specifically warned Defendants against providing access to the redacted portions of the disputed documents to their experts. (Plaintiffs' Mem., Ex. F, Calia Sept. 26, 2006 letter to Gracey.) Defendants cannot now be heard to claim prejudice through having done exactly what Plaintiffs warned against. Indeed, at its extreme, Defendants would be able to justify the use of any privileged material merely because one of their experts improvidently relied upon it after a request for its

return or destruction. In any event, Defendants offer no support for the proposition that the commercial success of galantamine as a treatment for Alzheimer's disease is affected by whether Janssen sought a patent for a product formulation of galantamine combined with another drug.

REDACTED

These two sections also relate to formulations of galantamine not within the scope of Janssen's IND/NDA for Razadyne IR, and are properly excluded from discovery on that basis. Defendants' assertion that because the Controlled Release (CR) formula of Razadyne is the subject of a separate ANDA and a separate lawsuit does nothing to change the import of the parties' agreement with respect to this litigation. Defendants may not unilaterally declare that the parties' agreement is moot because the CR formula is at issue in another case. In fact, the Stipulated Protective order specifically provides that confidential material shall be used "only for the purpose of *this* litigation." (Plaintiffs Mem. Ex. H, Stipulated Protective Order ¶ 3 (emphasis added).) As such, Defendants' refusal to return or destroy information related to Razadyne CR is a clear violation of this Court's order.

REDACTED

Another subject that the parties agreed would be excluded from discovery is information related to galantamine synthesis and product formulation. (See Ex. B, Calia Mar. 10, 2006 letter to Defense Counsel.) This section of text from the LCO Plan is one example of several that specifically relates to galantamine synthesis. Defendants' discussion of these sections misleading fails to mention the parties' agreement, but instead repeats Defendants' flawed mantra that scientific or business information cannot be privileged. This section (and those similar to it) are properly redacted by Plaintiffs.

II. Summary of Janssen Draft License Agreement (JAN RAZ 0177809 - JAN RAZ 0177812).

A. The Distribution of the Draft License Summary to Janssen Employees Did Not Affect the Privileged Nature of its Content.

It is well established, and undisputed by the parties, that the attorney-client privilege applies to corporate entities as well as to individuals. *See, e.g., Upjohn Co.* v. *United States,* 449 U .S. 383, 391-92 (1981). Courts have also recognized that intra-corporate distribution of legal advice relayed indirectly from counsel through corporate personnel does not negate the privilege. *See SCM Corp.* v. *Xerox Corp.,* 70 F.R.D. 508, 518 (D.Conn 1976) ("A privileged communication should not lose its protection if an executive relays legal advice to another who shares responsibility for the subject matter."). "This follows from the recognition that since the decision-making power of the corporate client may be diffused among several employees, the dissemination of confidential communications to such persons does not defeat the privilege." *Bank Brussels Lambert* v. *Credit Lyonnais (Suisse) S.A.,* 160 F.R.D. 437, 442 (S.D.N.Y. 1995).

Defendants' argument that the privileged nature of the Licensing Summary would have been destroyed by disclosure to any third parties is baseless. The Defendants offer no facts

to support their theory, but instead assert that the Court should allow Defendants access to the privileged portions of this document because its authors or recipients *may* have been third parties. To the contrary, Plaintiffs have confirmed that each of the persons identified as authors or recipients of the Licensing Summary were Janssen employees as of the date of the document, and that each of the recipients were directly involved in the potential license agreement that is the subject of the document. (Herridge Aff. at ¶ 8.) Plaintiffs are aware of no circumstances in which the document has been disclosed to any third parties. (Herridge Aff. at ¶ 8.)

B. The Redacted Portions of the Licensing Summary Contain Privileged Content.

As with the LCO Plan, Defendants cite no case law to refute Plaintiffs' assertion of privilege over the redacted portions of the Licensing Summary, the content of which was provided by in-house counsel to scientists and executives at Janssen for the purpose of conveying legal advice regarding the provisions of the proposed Shire license and the intellectual property landscape associated with galantamine. (Herridge Aff. at ¶ 7.)

The Licensing Summary was based on a draft version of the proposed agreement between Janssen and Shire and provided to individuals within Janssen prior to the execution of the final agreement. (Herridge Aff. at ¶ 8.) It appears that Defendants acknowledge that the Licensing Summary relates to a draft, as they themselves describe the document as "a summary of the *potential* licensing contract." (Def. Opp. at 23 (emphasis added).)

It is well established that a draft licensing agreement, and communications containing legal advice relating to such a draft agreement fall within the protection of the attorney-client privilege. *See Phillips Electronics North America Corp.* v. *Universal Electronics Inc.*, 892 F. Supp 108, 110 (D. Del. 1995) (finding that documents prepared by counsel for the purpose of facilitating a communication of advice to the client on the structure and terms for a

proposed licensing agreement, such as the terms of a proposed royalty rate, appear to be privileged).

Nevertheless, Defendants ignore the law and rely instead on only generalized and unsupported statements asserting that privilege does not apply because the Licensing Summary is of a "business nature." (Def. Opp. at 20-23.) Defendants' repeated mischaracterization of the Licensing Summary as "the Shire Business Memo" is equally unavailing. Here again, Defendants attempt to make truth through repetition. Simply referring to it as a business memo cannot remove the legal analysis and interpretation contained in the document, and cannot change the clearly privileged nature of the redacted information.[3]

CONCLUSION

Defendants' refusal to return or destroy these clearly privileged materials reflect a clear desire to seek an unfair advantage in this litigation in violation of the Stipulated Protective Order and the parties' prior agreement concerning the scope of discovery.

For the foregoing reasons, and for the reasons set forth in Plaintiffs' opening memorandum, Plaintiffs respectfully request that the Court compel the Defendants to return to Plaintiffs or destroy all copies of the unredacted versions of JAN RAZ 0192627 - JAN RAZ 0192641 and JAN RAZ 0177809 - JAN RAZ 0177812 within three business days of an Order

---

[3] Though the fact that the redacted portions of the Licensing Summary constitute the legal analysis and interpretation of counsel is sufficient to establish protection under the attorney-client privilege, the individual sections set forth by Defendants also contain legal evaluation and guidance by counsel of the scope and duration of patent protection, as well as information related to the synthesis of galantamine. As discussed above with respect to the LCO Plan, the nature of such content is yet another reason why the redacted portions of the Licensing Summary are properly excluded from discovery.

from the Court, as well as to destroy all summaries, notes, and the like on the basis of these documents as required by Paragraph 29 of the Stipulated Protective Order.

ASHBY & GEDDES

/s/ John G. Day

Steven J. Balick (I.D. # 2114)
John G. Day (I.D. # 2403)
Tiffany Geyer Lydon (I.D. #3950)
222 Delaware Avenue, 17th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888
sbalick@ashby-geddes.com
jday@ashby-geddes.com
tlydon@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Kurt G. Calia
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
202-662-6000

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

Dated: October 30, 2006

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civil Action No. 05-356-KAJ (consolidated)

AFFIDAVIT OF PETER HERRIDGE, ESQ.

I, PETER HERRIDGE, being duly sworn and having knowledge of the facts set forth herein, deposes and says as follows:

1. I am in-house counsel to Johnson & Johnson, the parent company of Plaintiffs Janssen Pharmaceutica N.V. and Janssen L.P (collectively, "Plaintiffs"). I submit this Affidavit in support of Plaintiffs' Motion to Compel the Return or Destruction of Inadvertently Produced Privileged Documents (hereinafter "Plaintiffs' Motion").

2. I understand that in opposing Plaintiff's Motion, Defendant Barr (joined by co-Defendant, Alphapharm) claims that two documents – a Life Cycle (LCO) Plan (JAN RAZ 0192627-641) and an Executive Licensing summary (JAN RAZ 0177809-812) – are not privileged. For the reasons set forth below, based on my investigation as to the origin and purpose of these documents and how they were handled by Janssen, Defendants claim is incorrect.

The Life Cycle (LCO) Plan – JAN RAZ 0192627-641

3. Upon learning of the inadvertent production of privileged portions of the Life Cycle (LCO) Plan, JAN RAZ 0192627-641 (hereinafter "LCO Plan"), I conducted an investigation as to the manner in which the document was created and the purpose for which it was used by Janssen.

4. Specifically, I contacted Janssen's in-house patent counsel, Mary Appollina, and discussed the document with her. In that discussion, Ms. Appollina informed me that the document was created in Janssen's facilities in Titusville, NJ, and that different persons contributed to different portions of the document. When I directed her to the specific portions of the document related to patent issues (which I understand our counsel has redacted in producing a second, redacted version of the document), she informed me that she was responsible for the content, which she provided to scientists and executives at Janssen for the purpose of conveying legal advice regarding the intellectual property landscape associated with galantamine, the active ingredient of Razadyne. Ms. Appollina also informed me that a colleague at Janssen Pharmaceutica N.V., a Belgian patent agent named Luc Quaghebeur resident in Janssen's Belgium offices, assisted her in preparation of the document, which he did at the direction of Ms. Appollina and Filip Verhoeven, the Belgian lawyer to whom Mr. Quaghebeur reports. While Mr. Quaghebeur assisted Ms. Appollina, she was responsible for the content of each portion of the document that our litigation counsel has redacted on the basis of privilege.

5. The LCO Plan is a highly confidential, internal Janssen document. We are aware of no circumstances in which it – redacted or otherwise – has been disclosed to anyone outside of Janssen (other than as a document produced in this litigation).

Executive Licensing Summary – JAN RAZ 0177809-812

6. Upon learning of the inadvertent production of privileged portions of the Executive Licensing Summary – JAN RAZ 0177809-812 (hereinafter "Licensing Summary"), I conducted an investigation as to the manner in which the document was created and the purpose for which it was used by Janssen.

7. Specifically, I contacted Janssen's in-house counsel, Filip Verhoeven in our Leuven, Belgium offices, and discussed the document with him. (Mr. Verhoeven is a lawyer registered with *Institut des Juristes d'enterprise / Instituut voor Bedrijfsjuristen*.) In that discussion, Mr. Verhoeven informed me that the three authors identified on the first page solicited content from a variety of sources in creating the document, and that they solicited content concerning the legal implications of the proposed Shire license (and other information concerning the patent landscape regarding galantamine) from him. When I directed him to the specific portions of the document related to patent issues (which I understand our counsel has redacted in producing a second, redacted version of the document), he informed me that he was responsible for the content, which he provided to the scientists and executives at Janssen identified on the first page for the purpose of conveying legal advice regarding the provisions of the proposed Shire license and the intellectual property landscape associated with galantamine. Mr. Verhoeven informed me that he was solely responsible for the content of each portion of the document that our litigation counsel has redacted on the basis of privilege.

8. The Licensing Summary was provided to individuals within Janssen prior to the execution of the final agreement between Janssen and Shire (and the only recipients – members of the Pharmaceutical/Diagnostics Group Operating Committee and Executive Committee – were directly involved in the potential license agreement). I further confirm that each of the persons identified as authors and recipients of the document were Janssen employees as of the date of the document. Accordingly, Janssen views this document as highly confidential. We are aware of no circumstances in which it – redacted or otherwise – has been disclosed to anyone outside of Janssen (other than as a document produced in this litigation).

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this October 30, 2006:

Peter Herridge

Peter Herridge

SUBSCRIBED AND SWORN TO
before me this 30th day of October 2006,

Sheila R. Cole
NOTARY PUBLIC
My Commission Expires:

SHEILA R. COLE
A NOTARY PUBLIC OF NEW JERSEY
My Commission Expires Oct. 18, 2010

EXHIBIT B

COVINGTON & BURLING

1201 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004-2401
TEL 202 662.6000
FAX 202 662 6291
WWW COV COM

WASHINGTON
NEW YORK
SAN FRANCISCO
LONDON
BRUSSELS

KURT G CALIA
TEL 202 662 5602
FAX 202 778.5602
KCALIA@ COV COM

March 10, 2006

VIA E-MAIL and FIRST CLASS MAIL

Defense Counsel
Attached Service List

Re: In re: '318 Patent Infringement Litigation; Civil Action No. 05-356-KAJ (consolidated)

Dear Counsel:

The purpose of this letter is to follow-up on the parties' February 13, 2006 telephonic conference about discovery in this matter. To date, we have not received any additional information from the defendants, with the exception of a letter from Mylan's counsel which we received earlier this week (and to which we will respond under separate cover). We would appreciate responses from the remaining defendants as to the various issues we raised about defendants' document production efforts, detailed in my earlier correspondence from January and February.

While each defendant has different document requests served on Plaintiffs, there is a great deal of overlap, and so we will address production issues with respect to categories of documents rather than attempt a request-by-request recitation of Plaintiffs' positions with respect to each of the defendants' individual requests. To the extent that any defendant has a concern with respect to a particular request not covered by the points set forth below (which we endeavored to make as comprehensive as possible), please let us know.

Limitation to NDA/ANDA Products. As you will recall, during the February 13 call, it was suggested by defendants that the parties limit their respective production of documents to only documents that relate to the specific products that are the subject of Janssen's New Drug Application ("NDA") 21-169 and the defendants' Abbreviated New Drug Applications ("ANDAs"). You will recall that defendants raised this in the context of our correspondence in which Plaintiffs requested the production of documents related to other Alzheimer's treatment products (actual or proposed) and other products containing galantamine – requests to which each of the defendants objected as overly broad, among other objections. Plaintiffs are willing to agree to the limitation proposed by defendants. However, as we have made clear, we reserve our

right to introduce evidence of other products that relates to objective considerations of nonobviousness. Accordingly, Plaintiffs will produce documents related to the Reminyl®/Razadyne® product that is the subject of NDA 21-169 (subject to the other limitations set forth in this letter) and not to other products. To date, we have produced over 35,000 pages of responsive documents that relate to the Reminyl®/Razadyne® product and to the '318 patent, and we anticipate producing additional documents. We hope to complete our paper production by the end of March.

Exclusion of Galantamine Synthesis/Product Formulation. During the February 13 telephone conference, we also discussed the possibility of excluding from discovery information related to galantamine synthesis and product formulation as not relevant to the present dispute. Lynn Ulrich suggested that the parties exchange the Table of Contents for the NDA and ANDAs, respectively, and identify the portions of those respective filings that will not be produced consistent with this limitation. To that end, we have enclosed with this letter the Index for NDA 21-169, and we state that Plaintiffs will exclude from their production of this NDA Sections 3.4 and the entirety of Section 4, with the exception of Section 4.6.3 entitled "Draft Labeling." We request that defendants send us the indexes for their respective ANDAs and identify the sections that will not be produced in a manner consistent with this agreed-upon limitation.

Regulatory Documents. During our call, counsel for certain defendants raised questions concerning the scope of Plaintiffs' production of regulatory documents. Consistent with the position set forth above, we will produce NDA 21-169, as well as Janssen's Investigational New Drug application ("IND") 51,538, except as to any portions that relate to synthesis or formulation information, to the extent they exist. Plaintiffs will also produce any other documents provided to or received from FDA related to the NDA or IND, to the extent such documents exist and can be located by means of a reasonably diligent search. Plaintiffs will not, however, produce any documents related to efforts to obtain regulatory approval outside of the United States. Such information is not reasonably calculated to lead to the discovery of admissible evidence, and the production of it would be quite burdensome to Plaintiffs.

Foreign Patents/Licenses/Disputes. We have also been asked to produce documents related to Plaintiffs' foreign patents and patent applications, licenses regarding such patents and applications, and disputes related to them. Plaintiffs have produced and will produce non-privileged documents related to foreign counterparts to the '318 patent, as well as other documents related to the licensing of the '318 patent and any disputes related to that patent. Plaintiffs also agree to produce, to the extent not already produced, the pleadings in the Waldheim matter in Austria. But Plaintiffs believe that a production of documents beyond these document categories would be overly burdensome and not reasonably calculated to lead to the discovery of

admissible evidence in this case. We will look again to make sure that all such documents have been either produced or identified on a privilege log, as appropriate.

Marketing Information. Plaintiffs agree to produce the master marketing file for the Reminyl®/Razadyne® product – i.e., the official file that contains the marketing material for this product maintained by Janssen to address any inquiries from FDA, in the event that they were to arise. This amounts to a substantial amount of material – on the order of approximately 20-30 boxes' worth – and should contain all information that is reasonably calculated to lead to the discovery of admissible evidence in this case. Janssen also has voluminous files that contain information that could be fairly characterized as related to marketing (e.g., adverse event reports, case report forms, and voluminous raw clinical data). While we do not believe that these documents are relevant to this case, we are willing to make them available for inspection should defendants wish to look at them. Because the volume is extraordinary – on the order of 1200 boxes or more – we will make these materials available for inspection should the defendants be interested in reviewing this material.

Documents Relating to Physician Prescribing Factors. During our February 13 call, we identified this category of documents as related to the objective considerations of nonobviousness and reiterated our request that defendants produce responsive documents. Plaintiffs will produce documents located by means of a reasonably diligent search and expect defendants to do the same.

Bioequivalence Information. I raised the production of bioequivalence-related information by defendants during the February 13 call, as has been requested in Plaintiffs' document requests. Plaintiffs are willing to withdraw its demand for the production of such documents by defendants upon confirmation that you will not rely on any bioequivalence-related information at trial.

Miscellaneous Requests from Defendants. During our call, defendants raised a number of additional requests, to which we respond as follows:

- We will supplement our interrogatory answers identifying the applicable objective considerations of nonobviousness. In so doing, we are hampered by the lack of production of related information by defendants, but we will nevertheless provide a supplemental response at this time while reserving the right to supplement further once defendants have complied with their discovery obligations in this matter.

- We will also supplement our interrogatory answers concerning Plaintiffs' claim construction position.

- While we believe we already provided you with the Bates ranges for the documents produced from the Ladas & Perry files, we identify them again as: SYN RAZ 0000806-0004318; SYN RAZ 0015198-0018866; and, SYN RAZ 0024999-0025308.

- We believe that we have produced all non-privileged communications between Janssen and Dr. Bonnie Davis related to the document categories for which we have indicated we will produce responsive documents. If Plaintiffs identify additional such documents, we will produce them promptly.

- We are not entirely clear as to the nature of the request that we produce an "internal copy" of the file history. Nevertheless, we confirm that we have produced a copy of the file history as it currently exists in the files of Ladas & Perry.

- We have produced or will produce any non-privileged documents (or log on a privilege log any privileged documents) related to Janssen's listing of the '318 patent in the Orange Book that we can locate by means of a reasonably diligent search.

- You have asked that we produce Synaptech's SEC filings from 1986 to the present. Because Synaptech is not a publicly traded company, we do not have any documents to produce.

- Except as to documents created in relation to this litigation, we will produce or log on a privilege log documents related to any analyses of the '318 patent and to any analyses of whether the Reminyl®/Razadyne® product is covered by it to the extent they exist and can be located by means of a reasonably diligent search.

- To the extent they exist and can be located by means of a reasonably diligent search, we will produce any employment agreements that Dr. Bonnie Davis had at the time of the conception or reduction to practice of the invention.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

Kurt Calia clb

Kurt G. Calia

Enclosure (via e-mail only)

cc: Steven Balick, Esq. (via email only)

SERVICE LIST

By Electronic Mail:	By Electronic Mail:
William A Rakoczy *(wrakoczy@rmmslegal.com)* Christine J Siwik *(csiwik@rmmslegal.com)* Amy D. Brody *(abrody@rmmslegal.com)* Lara Monroe-Sampson *(lmonroe-sampson@rmmslegal.com)* **Rakoczy, Molino, Mazzochi, Siwik LLP** 6 West Hubbard Street, Suite 500 Chicago, IL 60610 312.527.2157/phone; 312.527.4205/fax	Mary B Matterer *(mmatterer@morrisjames.com)* **Morris James Hitchens & Williams LLP** 222 Delaware Avenue 10th Floor P.O. Box 2306 Wilmington, DE 19899-2306 302.888.6800/phone; 302.571.1750/fax
Counsel for Defendants Mylan Pharmaceuticals Inc. & Mylan Laboratories Inc.	

By Electronic Mail and First Class Mail:	By Electronic Mail:
Edward C. Donovan *(edonovan@kirkland.com)* Karen M. Robinson *(krobinson @kirkland.com)* Corey J. Manley *(cmanley@kirkland.com)* **Kirkland & Ellis LLP** 655 Fifteenth Street, NW Suite 1200 Washington, DC 20005-5793 202.879.5000/phone; 202.879.5200/fax	Josy W. Ingersoll *(jingersoll@ycst.com)* John W. Shaw *(jshaw@ycst.com)* **Young Conaway Stargatt & Taylor LLP** The Brandywine Building 1000 West Street 17th Floor Wilmington, DE 19899-0391 302.571.6600/phone; 302.571.1253/fax
Counsel for Defendants Teva Pharmaceuticals USA, Inc. & Teva Pharmaceuticals Industries Ltd.	

Taras A. Gracey *(tgracey@winston.com)* Lynn M. Ulrich *(lulrich @winston.com)* Brian L. Franklin *(bfranklin@winston.com)* **Winston & Strawn LLP** 35 West Wacker Drive Chicago, IL 60601 312.558.5600/phone; 312.558.5700/fax	
Counsel for Defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.	

Barbara S. Wahl *(wahl.barbara@arentfox.com)* Richard J. Berman *(berman.richard@arentfox.com)* D. Jacques Smith *(smith.jacques@arentfox.com)* Janine A. Carlan *(carlan.janine@arentfox.com)* John K. Hsu *(hsu.john@arentfox.com)* **Arent Fox PLLC** 1050 Connecticut Avenue, NW Washington, DC 20036-5339 202.857.6000/phone; 202.857.6395/fax	Philip A. Rovner *(provner@potteranderson.com)* **Potter Anderson & Corroon LLP** 1313 N. Market Street Hercules Plaza, 6th Floor P.O. Box 951 Wilmington, DE 19899-0951 302.984.6000/phone; 302.658.1192/fax
Counsel for Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.	

Robert J. Gunther, Jr *(robert.gunther@lw.com)* James P Barabas *(james.barabas@lw.com)* **Latham & Watkins LLP** 885 Third Avenue, Suite 1000 New York, NY 10022-4834 212 906.1200/phone; 212.751 4864/fax	Richard D. Kirk *(rkirk@bayardfirm.com)* **The Bayard Firm** 222 Delaware Avenue, Suite 900 P.O. Box 25130 Wilmington, DE 19899 302.655.5000/phone; 302.658.6395/fax
Counsel for Defendants Purepac Pharmaceutical Co. & Alpharma, Inc.	

EXHIBIT C

From: Calia, Kurt
Sent: Monday, April 17, 2006 11:06 AM
To: Edward C. Donovan (edonovan@kirkland.com)
Cc: Alan Bernstein (abernstein@crbcp.com); Amy D. Brody (abrody@rmmslegal.com); Anne Shea Gaza (gaza@rlf.com); Barbara S. Wahl (wahl.barbara@arentfox.com); Brian L. Franklin (bfranklin@winston.com); Christine J. Siwik (csiwik@rmmslegal.com); Corey J. Manley (cmanley@kirkland.com); D. Jacques Smith (smith.jacques@arentfox.com); Edward C. Donovan (edonovan@kirkland.com); Frederick L. Cottrell III (cottrell@rlf.com); James P. Barabas (james.barabas@lw.com); Janine A. Carlan (carlan.janine@arentfox.com); John G. Day (jday@ashby-geddes.com); John K. Hsu (hsu.john@arentfox.com); John W. Shaw (jshaw@ycst.com); Josy W. Ingersoll (jingersoll@ycst.com); Karen M. Robinson (krobinson@kirkland.com); Lara Monroe-Sampson (lmonroe-sampson@rmmslegal.com); Lynn M. Ulrich (lulrich@winston.com); Mary B. Matterer (mmatterer@morrisjames.com); Mona Gupta (mgupta@crbcp.com); Philip A. Rovner (provner@potteranderson.com); Richard D. Kirk (rkirk@bayardfirm.com); Richard J. Berman (berman.richard@arentfox.com); Robert J. Gunther Jr. (robert.gunther@lw.com); Steven J. Balick (sbalick@ashby-geddes.com); Stuart Sender (ssender@budd-larner.com); Taras A. Gracey (tgracey@winston.com); William A. Rakoczy (wrakoczy@rmmslegal.com)
Subject: In re: '318 Patent Litigation

Ed:

As a follow-up to our earlier telephone conversation, I had the chance to circle back to George Pappas this morning, and here's where we are on the "other products" discovery that came up during last week's discovery hearing. Plaintiffs are willing to forego discovery from the parties on all "other products" -- i.e., products other than the subject of the ANDAs seeking approval for a generic version of Razadyne. Defendants agree that Plaintiffs will not be obligated to produce discovery concerning products other than the subject of its NDA -- i.e., Razadyne. Plaintiffs reserve the right, however, to present evidence concerning the failure of others, including defendants, to develop Alzheimer treatment drugs other than those which are the subject of defendants' ANDAs.

With this understanding, we believe that this dispute about "other products" is resolved. Please let us know if you agree.

Sincerely,

Kurt G. Calia
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004-2401
202.662.5602 (v); 202.778.5602 (f)
kcalia@cov.com; www.cov.com

CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of November, 2006, the attached **REDACTED PUBLIC VERSION OF PLAINTIFFS' REPLY MEMORANDUM SUPPORTING MOTION SEEKING RETURN OR DESTRUCTION OF PRIVILEGED DOCUMENTS** was served upon the below-named counsel of record at the address and in the manner indicated:

John C. Phillips, Jr., Esquire — HAND DELIVERY
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806

Lynn M. Ulrich, Esquire — VIA ELECTRONIC MAIL
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601

Frederick L. Cottrell, III, Esquire — HAND DELIVERY
Richards, Layton & Finger
One Rodney Square
Wilmington, DE 19801

Alan H. Bernstein, Esquire — VIA ELECTRONIC MAIL
Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.
1635 Market Street, 12th Floor
Philadelphia, PA 19103

/s/ John G. Day

John G. Day